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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,371	10/09/2003	Randy Westlund	GUID.077PA	6103

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EXAMINER	
ALTER, ALYSSA MARGO	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,371	WESTLUND ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 67-74 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 18, 2008.

Response to Arguments

Applicant's arguments, see page 8, filed July 18, 2008, with respect to the rejection(s) of claim(s) 1-26 under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Cohen (US 5,336,252).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what components the Applicant considers "myocardium penetrating components" since the "myocardium penetrating components" are not positively recited in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6, 8-9, 12-14, 16-19 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,336,252). Cohen discloses the implantation of cardiac leads in the myocardium via a lead introducing system. The introducing system, as seen in figures 18 and 19, includes a guide wire that has a retractable needle tip, a dilator and dilator sheath. Since the guide wire has a needle tip, the examiner considers it to be a piercing needle.

As to claims 4-6 24-26, "Referring to FIG. 18, a flexible, dilator 130 having a blunt, tapered end 132 and sheath 136 next are slid over the wire guide 108 and advanced into the pericardium. The dilator is preferably formed of a polymeric material, such as polyurethane, and has a bore 134 which provides a generally close, sliding fit over the wire guide 108. For example, the dilator 130 may have a wall thickness of 4.5 mm and an outside diameter of 10 mm. The tapered, blunt-shaped distal end 132 of the dilator, when advanced into the pericardial space 109, dilates the hole 113 previously cut through the pericardium. Increasing the size of the pericardium access hole 113 is desirable in order to facilitate subsequent entry of the defibrillation leads through the hole.

As shown in FIGS. 18 and 19, after the hole 113 through the pericardium is dilated, the semi-rigid sheath 136 is advanced so that the distal end 138 of the sheath is positioned within the pericardial space 109 and held there by deploying the sheath anchor 137. Then, the dilator 130 is withdrawn, as shown in FIG. 20. A defibrillation lead ("lead") 140, shown in FIG. 21, is advanced through the sheath so that the distal end of the lead is positioned within the pericardial space 109" (col.14, lines 10-32).

As to claim 16, the examiner considers the fixation element, as seen in figure 24-25, to be a clip.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> This application currently names joint inventors.

In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 20 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (5,336,252). Cohen discloses the introducer system entering the myocardium at a shallow angle, which the examiner considers to be about 5 to 45 degrees. Furthermore, the examiner also

considers the introducer system to penetrate the myocardium at a depth with the range of about 1mm to about 10mm.

In the alternative, although the examiner considers Cohen to disclose a shallow angle between 5 and 45 degrees and within a depth of about 1mm to about 10mm above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shallow angle and depth, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233 (see MPEP 2144.05).

2. Claims 9-11, 15 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (5,336,252). Cohen discloses the claimed invention except for the helical fixation or suture fixation element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fixation element as taught by Cohen with a helical fixation element or a suture in order to provide the predictable results of affixing the lead to the myocardium. Furthermore, it was known in the art at the time the invention was made to employ helical fixation elements and sutures as attachment means for implantable medical devices.

As to claims 21-23, Cohen discloses the claimed invention except for passing the lead over the piercing needle. While Cohen discloses removing the guide wire and delivering the lead through the dilating sheath, it is well known in the art to implant a lead into the body via a guide wire. Furthermore, such a modification to place the lead

over the guide wire would provide the predictable results of enabling the clinician to steer the lead into the desired location.

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen (5,336,252) in view of Bourgeois et al. (US 5,716,392). Cohen discloses the claimed invention except for the lead eluting a steroid from the lead. Bourgeois et al. discloses a medical lead that elutes a steroid into the myocardium. It would have been obvious to one having ordinary skill in the art to modify the lead as taught by Cohen with the ablilty to elude a steroid as disclosed by Bourgeois et al. in order to provide the predictable results of providing the patient with a steroid in order to modify the immune response of the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762